

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Kerry Zang et al.
Serial No.: 10/777,514
Filing Date: February 11, 2004
Group Art Unit: 3738
Confirmation No. 5263
Examiner: Cheryl L. Miller
Title: CONICAL, THREADED SUBTALAR IMPLANT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

APPEAL BRIEF

Appellants have appealed to the Board of Patent Appeals and Interferences from the final office action issued November 4, 2009 ("*Office Action*") and the advisory action dated February 8, 2010 ("*Advisory Action*") finally rejecting Claims 40-44, 46-57, 62, 63, and 65-72. Appellants filed a Notice of Appeal on May 8, 2010 along with a Pre-Appeal Brief Request for Review. A Notice of Panel Decision from Pre-Appeal Brief Review issued April 26 ("*Notice*"), 2010 indicated that there is at least one actual issue for appeal. Appellants respectfully submit this Appeal Brief with the statutory fee of **\$540.00**.

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Real Party In Interest

The real party-in-interest for this Application is OSTEOMED L.P., a Delaware limited partnership, by virtue of a chain of title from the inventors to the current assignee, as shown below:

1. From: KERRY ZANG
SHAHER A. AHMAD
LISA R. THORNHILL

To: OSTEOMED L.P.

Assignment recorded at Reel/Frame 015450 / 0668, on June 7, 2004.

Related Appeals and Interferences

Appellants, the undersigned Attorney for Appellants, and the Assignee know of no applications on appeal that may directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

Status of Claims

Claims 40-44, 46-57, 62, 63, and 65-72 were finally rejected in a Final Office Action dated November 4, 2009 ("*Office Action*") and in an Advisory Action dated February 8, 2010 ("*Advisory Action*"). Appellants present Claims 40-44, 46-57, 62, 63, and 65-72 for appeal and set forth these claims in Appendix A. All claims presented for appeal are shown in Appendix A, attached hereto, along with an indication of the status of those claims.

Status of Amendments

All amendments submitted by Appellants were entered by the Examiner prior to the mailing of the *Office Action*.

Summary of Claimed Subject Matter

Embodiments of the present invention relate generally to the field of biomedical implants and in particular to conical, threaded subtalar implants and methods for manufacturing the same. See e.g., *Application*, page 1, lines 4-5.

Pes planus, or pes valgo planus, is a deformity producing a severe flat foot. The deformity occurs largely at one particular joint, the talocalcaneal articulation, which is the joint between the talus and calcaneus bones in the foot. See e.g., *Application*, page 2 lines 2-4.

In many cases, the symptoms of pes valgo planus may be treated using conservative measures such as anti-inflammatory medications, rest, ice, shoe inserts or orthotic supports, or even ankle-foot braces. However, in some cases, such measures prove inadequate and the person may continue to experience severe foot or ankle pain or suffer from night cramps, pain when walking and/or standing, or lower back and knee pain. In such cases, a subtalar implant may be used to correct the flatfoot deformity while maintaining mobility of the subtalar joint. The subtalar implant is a small device that is inserted into a small opening in the talocalcaneal joint called the sinus tarsi. The placement of the implant restores the arch by preventing the displacement of the talus and by preventing the foot from rolling-in (pronating). In some cases, tissue may grow around the implant which helps hold the implant in place within the sinus tarsi. See e.g., *Application*, page 2 line 25 - page 3 line 6.

The present invention provides a conical, threaded medical implant adapted for implantation within a person's body to limit motion in a joint having excessive mobility. See e.g., *Application*, page 4 lines 2-4. For example, in certain embodiments in which the medical implant is adapted for use as a subtalar implant, the implant may be inserted via a subtalar arthroereisis operation into the sinus tarsi of a person suffering from pes valgo planus. Once inserted, the implant may reduce calcaneal eversion to a desirable level and block excessive displacement of the talus, thus correcting the pes valgo planus condition. In addition, the implant may allow normal motion of the subtalar joint while correcting the pes valgo planus, thus allowing the person to function normally. See e.g., *Application*, page 4 lines 13-19.

FIGURES 1A-1C illustrate a subtalar implant 10 in accordance with one embodiment of the present invention. In particular, FIGURE 1A illustrates an external side view of

implant 10, FIGURE 1B illustrates a cross-sectional view of implant 10 taken along line A-A of FIGURE 1A, and FIGURE 1C illustrates an external end view of implant 10. In general, subtalar implant 10 may be inserted into the sinus tarsi of a person suffering from pes valgo planus in a subtalar arthroereisis operation. See e.g., *Application*, page 7 lines 9-15; see also Figures 1A-1C and Figure 4.

As shown in FIGURE 1A, subtalar implant 10 includes a substantially conical body 12, a plurality of threads 14, and an engagement 16. Threads 14 are formed around the exterior surface 18 of body 12 and extend from a leading end 20 to a trailing end 22 of body 12. Threads 14 are provided to guide the insertion of implant 10 into, and to help secure implant 10 within, the sinus tarsi of a person. Each thread 14 includes a leading flank 24, a trailing flank 26, and a crest 28 connecting leading flank 24 with trailing flank 26. A root 30 is formed between each pair of adjacent threads 14 and connects the leading end 20 of one thread with the trailing end 22 of an adjacent thread 14. See e.g., *Application*, page 7 lines 19-27.

As shown in FIGURE 1B, engagement 16 is formed in trailing end 22 of body 12 and is coaxial with a bore 32 extending from leading end 22 of body 12 to engagement 16. Engagement 16 is adapted to receive and be engaged by an implantation tool such that implant 10 may be rotated about a longitudinal axis 34 for the implantation of implant 10 into the sinus tarsi. In this embodiment, engagement 16 comprises a recess having a hexagonal portion 36 integrated with a cylindrical portion 38 such that engagement 16 is adapted to receive and be engaged by a hex-head implantation tool, for example. See e.g., *Application*, page 9 line 28 - page 10 line 5.

FIGURE 1B also illustrates various dimensions that define the shape of implant 10. For example, body 12 is at least partially defined by a length 40, a leading end diameter 42, and a taper angle 44. Threads 14 are at least partially defined by a thread angle 50, a pitch 52, a thread height 54, a root width 56, and a crest width 58. A variety of implants 10 may be formed in various sizes and having various values for the dimensions listed above. For example, length 40, leading end diameter 42, and taper angle 44 may be appropriately sized to fit within the sinus tarsi of a person. Since the sinus tarsi of different people may have a range of sizes, a variety of implants 10 may be provided having a range of lengths 40, leading end diameters 42, and taper angles 44 such that an appropriate implant 10 may be selected for

each person based on the size and shape of that person's sinus tarsi. See e.g., *Application*, page 8 lines 9 - 19. Similarly, a range of taper angles 44 may be used in various implants 10 to correspond with a range of taper angles of the sinus tarsi of various people. See e.g., *Application*, page 8 lines 25 - 26.

The dimensions defining threads 14 may be selected based on a number of objectives, such as to provide implant 10 that may be easily threaded into the sinus tarsi and adequately secured in place within the sinus tarsi, and to limit or avoid pain to the patient, for example. In certain embodiments, threads 14 may be formed such that they are sharp enough to adequately secure implant 10 in place within a person's sinus tarsi, yet not sharp enough to cause pain to the person. In particular, the ratio of crest width 58 to one or more other thread dimensions, such as pitch 52 or thread height 54 for example, may be selected in order to provide these objectives. See e.g., *Application*, page 9 lines 8-15. In particular embodiments, an implant 110 may have a substantially constant thread height 154 and a substantially constant pitch 152 as illustrated, for example, in FIGURE 4. See e.g., Amendment to Specification in Office Action response dated 04/28/2008 page 3; see also Figure 4.

Taken together, FIGURES 1B and 1C illustrate engagement 16 and bore 32 formed in body 12 of implant 10. Bore 32 is at least partially defined by a bore diameter 60. Hexagonal portion 36 of engagement 16 is defined by a width 62 and depth 64 and cylindrical portion 38 engagement 16 is defined by a diameter 66 and depth 68. See e.g., *Application*, page 10 lines 9 - 13.

With regard to the claims currently under Appeal, Appellants provide the following concise explanation of the subject matter recited in the claim elements. For brevity, ***Appellants do not necessarily identify every portion of the Specification and drawings relevant to the recited claim elements.*** Additionally, this explanation should not be used to limit Appellants' claims but is intended to assist the Board in considering the Appeal of this Application.

For example, Independent Claim 40 recites the following:

A medical implant (e.g., *Application*, page 1 lines 4-5), comprising:

a headless body configured to fit snugly into a sinus tarsi of a subtalar joint in a human foot (e.g., *Application*, page 7 lines 2-4; page 8 lines 9-11; and Figures 1A-1C and 4), the body comprising:

- a first end having a first diameter (e.g., *Application*, page 8 lines 9-11; Figures 1A-1C and 4);

- a second end having a second diameter (e.g., *Application*, page 8 lines 9-11; Figures 1A-1C and 4);

- at least one continuous and uninterrupted thread including a crest with a substantially flat surface and having a substantially constant thread height and helically traversing a length of an exterior surface of the body, the length spanning from the first end to the second end (e.g., *Application*, page 7 lines 20-22; Figures 1A-1C and 4);

- a recessed engagement in the first end (e.g., *Application*, page 7 lines 28-30; Figures 1B-1C); and wherein:

- a circumference of the exterior surface tapers from the first diameter to the second diameter along the length of the body (e.g., *Application*, page 8 lines 9-11; Figures 1A-1C and 4); and

- the thread includes a leading flank spanning from the crest to a thread root and a trailing flank spanning from the crest to the thread root, the leading flank separated from the trailing flank by a narrowing clearance therebetween (e.g., *Application*, page 8 lines 23-27; Figures 1A-1B and 4).

As another example, Independent Claim 44 recites the following:

A medical implant (e.g., *Application*, page 1 lines 4-5), comprising:

- a body adapted for implantation into a sinus tarsi of a subtalar joint in a human foot (e.g., *Application*, page 7 lines 2-7; and Figures 1A-1C and 4), the body comprising:

- a first end having a first diameter (e.g., *Application*, page 8 lines 9-11; Figures 1A-1C and 4);

- a second end having a second diameter (e.g., *Application*, page 8 lines 9-11; Figures 1A-1C and 4);

- at least one continuous and uninterrupted thread including a crest with a substantially flat surface and having a substantially constant thread height and helically traversing a length

of an exterior surface of the body, the length spanning from the first end to the second end (e.g., *Application*, page 7 lines 20-22; Figures 1A-1C and 4); and

a recessed engagement in the first end (e.g., *Application*, page 7 line 28 - page 8 line 8; Figures 1B-1C), the recessed engagement comprising:

a hexagonal portion (e.g., *Application*, page 7 line 28 - page 8 line 8; Figures 1B-1C);

a cylindrical portion (e.g., *Application*, page 7 line 28 - page 8 line 8; Figures 1B-1C);

a countersink portion (e.g., *Application*, page 7 line 28 - page 8 line 8; Figures 1B-1C); and wherein:

a circumference of the exterior surface tapers from the first diameter to the second diameter along the length of the body (e.g., *Application*, page 8 lines 9-11; Figures 1A-1C and 4);

the taper angle is configured to minimize pressure points between the body and a talus bone and the body and a calcaneus bone when the body is implanted into the sinus tarsi (e.g., *Application*, page 8 line 25 - page 9 line 7; and

the thread includes a leading flank spanning from the crest to a thread root and a trailing flank spanning from the crest to the thread root, the leading flank separated from the trailing flank by a narrowing clearance therebetween (e.g., *Application*, page 8 lines 23-27; Figures 1A-1B and 4).

As another example, Independent Claim 55 recites the following:

A method of forming a medical implant (e.g., *Application*, page 1 lines 4-5), comprising:

configuring a headless body to fit snugly into a sinus tarsi of a subtalar joint in a human foot (e.g., *Application*, page 7 lines 2-4; page 8 lines 9-11; and Figures 1A-1C and 4), the body comprising:

a first end having a first diameter (e.g., *Application*, page 8 lines 9-11; Figures 1A-1C and 4);

a second end having a second diameter (e.g., *Application*, page 8 lines 9-11; Figures 1A-1C and 4);

forming at least one continuous and uninterrupted thread including a crest with a substantially flat surface and having a substantially constant thread height and helically

traversing a length of an exterior surface of the body, the length spanning from the first end to the second end (e.g., *Application*, page 7 lines 20-22; Figures 1A-1C and 4);

forming a recessed engagement in the first end (e.g., *Application*, page 7 lines 28-30; Figures 1B-1C); and wherein:

a circumference of the exterior surface tapers from the first diameter to the second diameter along the length of the body (e.g., *Application*, page 8 lines 9-11; Figures 1A-1C and 4); and

the thread includes a leading flank spanning from the crest to a thread root and a trailing flank spanning from the crest to the thread root, the leading flank separated from the trailing flank by a narrowing clearance therebetween (e.g., *Application*, page 8 lines 23-27).

As another example, Independent Claim 67 recites the following:

A method, comprising:

inserting into the sinus tarsi (e.g., *Application*, page 7 lines 1-7):

a body configured to fit snugly into a sinus tarsi of a subtalar joint in a human foot (e.g., *Application*, page 8 line 25 - page 9 line 4), the body comprising:

a first end having a first diameter (e.g., *Application*, page 8 lines 9-11; Figures 1A-1C and 4);

a second end having a second diameter (e.g., *Application*, page 8 lines 9-11; Figures 1A-1C and 4);

a recessed engagement in the first end (e.g., *Application*, page 7 line 28 - page 8 line 8; Figures 1B-1C);

a bore coaxial with the recessed engagement and extending from the recessed engagement to the second end (e.g., *Application*, page 7 lines 28-30; Figures 1B-1C);

at least one continuous and uninterrupted thread (e.g., *Application*, page 7 lines 20-22; Figures 1A-1C and 4) including:

a crest with a substantially flat surface and having a substantially constant thread height and helically traversing a length of an exterior surface of the body, the length spanning from the first end to the second end (e.g., *Application*, page 7 lines 20-22; Figures 1A-1C and 4); and

a leading flank inclined away from the second end and spanning from the crest to a thread root and a trailing flank inclined away from the first end and spanning from the crest

to the thread root, the leading flank and the trailing flank defining a thread angle (e.g., *Application*, page 8 lines 23-27; Figures 1A-1B and 4); and wherein

a circumference of the exterior surface tapers from the first diameter to the second diameter along the length of the body (e.g., *Application*, page 8 lines 9-11; Figures 1A-1C and 4); and

the thread is configured to secure the body into the sinus tarsi, and to limit pain caused to a patient by the thread once the body is inserted into the sinus tarsi (e.g., *Application*, page 9 lines 8-13).

As another example, Independent Claim 70 recites the following:

A medical implant (e.g., *Application*, page 1 lines 4-5), comprising:

a body configured to fit snugly into a sinus tarsi of a subtalar joint in a human foot (e.g., *Application*, page 7 lines 2-4; page 8 lines 9-11; and Figures 1A-1C and 4), the body comprising:

a first end having a first diameter (e.g., *Application*, page 8 lines 9-11; Figures 1A-1C and 4);

a second end having a second diameter (e.g., *Application*, page 8 lines 9-11; Figures 1A-1C and 4);

a recessed engagement in the first end (e.g., *Application*, page 7 line 28 - page 8 line 8; Figures 1B-1C);

a bore coaxial with the recessed engagement and extending from the recessed engagement to the second end (e.g., *Application*, page 7 lines 28-30; Figures 1B-1C);

at least one continuous and uninterrupted thread (e.g., *Application*, page 7 lines 20-22; Figures 1A-1C and 4) including:

a crest with a substantially flat surface and having a substantially constant thread height and helically traversing a length of an exterior surface of the body, the length spanning from the first end to the second end (e.g., *Application*, page 7 lines 20-22; Figures 1A-1C and 4); and

a leading flank spanning from the crest to a thread root and a trailing flank spanning from the crest to the thread root, the leading flank separated from the trailing flank by a narrowing clearance therebetween, the leading flank and the trailing flank defining a thread angle (e.g., *Application*, page 8 lines 23-27; Figures 1A-1B and 4); and wherein

a circumference of the exterior surface tapers from the first diameter to the second diameter along the length of the body (e.g., *Application*, page 8 lines 9-11; Figures 1A-1C and 4); and

the thread is configured to secure the body into the sinus tarsi, and to minimize pain caused to a patient by the thread once the body is inserted into the sinus tarsi (e.g., *Application*, page 9 lines 8-13).

Grounds of Rejection to be Reviewed on Appeal

Objections

1. Appellants request that the Board review the Examiner's objection to the Specification under 35 U.S.C. § 132.

Section 112 rejections

1. Appellants request that the Board review the Examiner's rejection of Claims 40-44, 46-57, 62-63, and 65-72 under 35 U.S.C. § 112, first paragraph.

Section 102 rejections

1. Appellants request that the Board review the Examiner's rejection of Claims 40-42, 44, 47, 50, 52-57, 62, 63, 66, and 70-72 under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 5,951,560 to Simon et al. ("*Simon*").

2. Appellants request that the Board review the Examiner's rejection of Claims 40-42, 44, 50, 52-57, 63, 66, 70, and 72 under 35 U.S.C. § 102(e) as allegedly being anticipated by U.S. Patent No. 7,608,105 to Pavlov et al. ("*Pavlov*").

3. Appellants request that the Board review the Examiner's rejection of Claims 40, 55, and 70-72 under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 3,726,180 to Rosan ("*Rosan*").

4. Appellants request that the Board review the Examiner's rejection of Claims 40-44, 47, 50, 52-57, 62-63, 66, 70, and 72 under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent Publication No. US 2002-0038123 by Visotsky et al. ("*Visotsky*").

5. Appellants request that the Board review the Examiner's rejection of Claim 72 under 35 U.S.C. § 102(b) as allegedly being anticipated by *Simon*.

6. Appellants request that the Board review the Examiner's rejection of Claim 43 under 35 U.S.C. § 102(b) as allegedly being anticipated by *Visotsky*.

Section 103 rejections

1. Appellants request that the Board review the Examiner's rejection of Claims 67-69 under 35 U.S.C. § 103(a) as allegedly being unpatentable over *Visotsky* in view of the knowledge of one of ordinary skill in the art.

2. Appellants request that the Board review the Examiner's rejection of Claim 69 under 35 U.S.C. § 103(a) as allegedly being unpatentable over *Visotsky* in view of the knowledge of one of ordinary skill in the art.

Argument

Objections to Specification

I. Appellants have not added new matter to the specification under 35 U.S.C. § 132.

The Examiner objects to the specification under 35 U.S.C. § 132 as allegedly containing new matter. Specifically, the Examiner argues “[a]lthough applicant appears to have support for a constant thread height and pitch, applicant does not appear to have support for the term ‘substantially’ constant.” See *Office Action*, page 2, lines 9-11. Appellants respectfully traverse this objection.

According to the M.P.E.P., “the fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed.” See *id.* at §2163.02. Moreover, “[i]n establishing a disclosure, applicant may rely not only on the specification and drawing as filed but also on the original claims if their content justifies it.” §608.04. Also, “[b]y disclosing in a patent application a device that inherently . . . has a property . . . a patent application necessarily discloses that function, theory or advantage, even though it says nothing explicit concerning it. The application may later be amended to recite the function, theory or advantage without introducing prohibited new matter.” § 2173.07(a).

Appellants respectfully contend one of ordinary skill in the art would appreciate Appellants’ specification supports substantially constant physical characteristics (e.g., thread pitch and the thread height) for example due to manufacturing imperfections or tolerances. Example support for this assertion may be found in Claim 14 as originally filed which recited “wherein the thread height of each of the one or more threads is 0.032 inches.” Additionally, originally filed Claim 14 stated, “the pitch of the one or more threads is 0.090 inches.” Each of those characteristics would be substantially constant due for example to manufacturing imperfections or tolerances.

Appellants also respectfully contend one of ordinary skill in the art would appreciate Appellants’ specification supports a tapered thread height as shown, for example, in

Figure 1B. For at least those reasons, Appellants respectfully request that the objections to the specification be withdrawn.

Section 112 Rejections

I. Claims 40-44, 46-57, 62-63, and 65-72 comply with 35 U.S.C. § 112, first paragraph.

The Examiner rejects Claims 40-44, 46-57, 62-63, and 65-72 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. Appellants respectfully traverse those rejections for the reasons stated below.

With respect to Claims 40-44, 46-57, 62-63, and 65-72, the Examiner asserts “applicant does not have support for the term ‘substantially’ which broadens the dimensions to a range such that adjacent threads may have slightly different dimensions.” See *Office Action*, page 3, lines 3-5. However, According to the M.P.E.P., “[b]y disclosing in a patent application a device that inherently . . . has a property . . . a patent application necessarily discloses that function, theory or advantage, even though it says nothing explicit concerning it. The application may later be amended to recite the function, theory or advantage without introducing prohibited new matter.” § 2173.07(a).

Appellants respectfully contend one of ordinary skill in the art would appreciate Appellants’ specification supports substantially constant physical characteristics (e.g., thread pitch and the thread height) for example due to manufacturing imperfections or tolerances. Consequently, Appellants respectfully request the Examiner to withdraw the associated rejections of Claims 40-44, 46-57, 62-63, and 65-72, under 35 U.S.C. § 112, first paragraph.

Section 102 Rejections

The Examiner, under 35 U.S.C. § 102(b), rejects as allegedly being anticipated: Claims 40-42, 44, 47, 50, 52-57, 62, 63, 66, and 70-72 by U.S. Patent No. 5,951,560 to Simon et al. (“*Simon*”), Claims 40, 55, and 70-72 by U.S. Patent No. 3,726,180 to Rosan, Sr. (“*Rosan*”), and Claims 40-44, 47, 50, 52-57, 62-63, 66, 70, and 72 by U.S. Patent Publication No. 2002/0038123 A1 by Visotsky et al. (“*Visotsky*”). The Examiner, under 35 U.S.C. § 102(e), further rejects Claims 40-42, 44, 50, 52-57, 63, 66, 70, and 72 as allegedly being anticipated by U.S. Patent No. 7,608,105 B2 to Pavlov (“*Pavlov*”). See *Office Action*, pages 3-5.

I. Claims 40-42, 44, 47, 50, 52-57, 62, 63, 66, and 70-72 are patentable under 35 U.S.C. § 102(b) over *Simon*.

a. *Simon* fails to disclose a “substantially constant thread height” as recited in Claims 40, 44, 55, and 70.

Claim 40 recites “at least one continuous and uninterrupted thread including a crest with a substantially flat surface and having a substantially constant thread height.” The Examiner rejects those limitations by pointing to a medical implant illustrated in Figure 2 of *Simon* and arguing, “. . . fig. 2, is considered substantially constant, there is a small taper, but appears to be just as tapered or ‘substantially constant’ as applicants show their threads in fig. 1a, 1b of the present application.” See *Office Action*, page 4, lines 1-3. The Examiner also argues that *Simon* has a “minimal taper angle” that amounts to a substantially constant thread height. See *Advisory Action*, page 2. Appellants respectfully disagree. The thread height of the alleged threads of *Simon* is not substantially constant. Rather, it is tapered.

Simon explains that “[t]he **tapered form** of the screws 10 and 30 facilitate an insertion thereof into the respective gaps G with a uniform turning force which remains fairly constant as the screw is inserted into the respective gaps G until the compression force begins to develop.” *Simon*, col. 5, lines 21-25. That is, *Simon* teaches that the intended purpose of the tapered thread height is to “facilitate an insertion . . . with a **uniform turning force** which remains fairly constant . . . until the compression force begins to develop.” *Id.* (emphasis added). Consequently, one of ordinary skill in the art would not be motivated to modify the tapered thread height of *Simon* to be substantially constant because doing so would render the thread inoperable for its intended purpose of facilitating insertion with uniform turning force until compression begins to develop.

According to the MPEP, “[i]f proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. See §2143.01(V). Additionally, the examination guidelines issued by the United States Patent and Trademark Office (“PTO”) in response to the U.S. Supreme Court’s recent decision in *KSR Int’l Co. v. Teleflex, Inc* state, in part, that “[t]he rationale to support a conclusion that the claim would have been obvious is that all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods *with no change in their respective*

functions....” Examination Guidelines for Determining Obviousness Under 35 U.S.C. 103 in View of the Supreme Court Decision in KSR International Co. v. Teleflex Inc., 72 Fed. Reg. 57526, 57529 (Oct. 10, 2007) (emphasis added). According to this standard, there is no motivation to modify the device of *Simon* to include anything other than a tapered thread height.

While the Examiner contends that Figures 1a and 1b of Appellants’ specification shows a substantially constant thread height, Appellants respectfully point out that that thread height is tapered. As explained in Appellants’ previous responses dated 04/28/2008 and 12/22/2008, Appellants’ specification includes support for both tapered (see e.g., Figures 1a and 1b) and substantially constant (see e.g., originally filed claims) thread heights.

Since *Simon* fails to disclose a “at least one continuous and uninterrupted thread . . . having a substantially constant thread height and helically traversing a length of an exterior surface of the body, the length spanning from the first end to the second end,” and since one of ordinary skill in the art would not have been motivated to modify the tapered threading on the device shown in that reference, Appellants respectfully contend that Claim 40 and its dependent claims (e.g., Claims 41-43, 46-54, and 72) are allowable over *Simon*. For analogous reasons, independent Claims 44, 55, and 70 and each of their respective dependent claims (e.g., Claims 56-57, 62-63, and 65-66 and Claim 71) are allowable over *Simon*.

II. Claims 40-42, 44, 50, 52-57, 63, 66, 70 are patentable under 35 U.S.C. § 102(e) over Pavlov.

a. *Pavlov*, fails to disclose a “continuous and uninterrupted thread . . . helically traversing a length of an exterior surface of the body, the length spanning from the first end to the second end” as recited in Claims 40, 44, 55, and 70.

Claim 40 recites “at least one continuous and uninterrupted thread . . . helically traversing a length of an exterior surface of the body, the length spanning from the first end to the second end.” The Examiner rejects those limitations by pointing to a medical implant illustrated in Figure 1 of *Pavlov* and arguing, “(plurality of individual threads, each one uninterrupted seen in fig. 1).” See *Office Action*, page 4, lines 10-11 (emphasis in original). However, the alleged thread of *Pavlov* is not uninterrupted. Rather, Pavlov explains that sections of the alleged thread are cut away:

These flutes are defined by the **sections 52 which are removed from the threads**. In a preferred embodiment, the flutes become narrower as they approach the proximal end 26 due to the fact that thread relief for purposes of self-tapping becomes less important as the cage reaches a final resting position.

Pavlov, Col. 3 line 65 - Col. 4, line 3. That is, *Pavlov* explicitly discloses that its alleged thread is interrupted by cut-away sections 52. Moreover, *Pavlov* explains that the intended purpose of the cut-away sections is to make the device "self-tapping." Consequently, one of ordinary skill in the art would not be motivated to modify the device of *Rosan* to include an uninterrupted thread because doing so would render the device inoperable for its intended purpose of being self-tapping.

While the Examiner also seems to contend that the above-quoted limitations of Claim 40 are disclosed by a "plurality of threads," "each one being uninterrupted," *see e.g.*, *Advisory Action*, page 2, Appellants respectfully point out that none of those alleged threads spans "from the first end to the second end" as recited by Claim 40. Consequently, the "plurality of threads" cited by the Examiner in *Pavlov* fails to disclose "at least one continuous and uninterrupted thread . . . helically traversing a length of an exterior surface of the body, the length spanning from the first end to the second end."

Since *Pavlov* fails to disclose "at least one continuous and uninterrupted thread . . . helically traversing a length of an exterior surface of the body, the length spanning from the first end to the second end," and since one of ordinary skill in the art would not have been motivated to modify the device of *Pavlov* to include an uninterrupted thread, Appellants respectfully contend that Claim 40 and its dependent claims (e.g., Claims 41-43, 46-54, and 72) are allowable over *Pavlov*. For analogous reasons, independent Claims 44, 55, and 70 and each of their respective dependent claims (e.g., Claims 56-57, 62-63, and 65-66 and Claim 71) are allowable over *Pavlov*.

III. Claims 40, 55, and 70-72 under 35 U.S.C. § 102(b) are patentable under 35 U.S.C. § 102(b) over *Rosan*.

a. *Rosan*, fails to disclose a "continuous and uninterrupted thread . . . helically traversing a length of an exterior surface of the body, the length spanning from the first end to the second end" as recited in Claims 40, 55, and 70.

Claim 40 recites "at least one continuous and uninterrupted thread . . . helically traversing a length of an exterior surface of the body, the length spanning from the first end to the second end." In the *Office Action*, the Examiner also relies on Figure 1 of *Rosan* to disclose these limitations. See *Office Action*, page 4, lines 20-22. However, the alleged thread 12 of *Rosan* does not "travers[e] a length of an exterior surface of the body, the length spanning from the first end to the second end" as recited in Claim 40. Rather, thread 12 ends at an "annular groove 15" that separates thread 12 from a pilot means 14 located at the end of the alleged implant of *Rosan*. As explained by *Rosan*, "[s]ituated between the lead thread 12c and pilot means 14 is an annular groove 15 which is formed by the bottom surface and top surface of said lead thread 12c and pilot means 14, respectively." See *Rosan* Col. 2 lines 42-45; see also Figures 1 and 4 (showing thread 12 ending at annular groove 15). Moreover, *Rosan* explains that the annular groove 15 is necessary to the operation of the device. As explained by *Rosan*:

Groove 15 has a constant axial height and is position forward of lead thread 12c and rearward of pilot means 14 **so that as workpiece material or debris is loosened during the tapping operation, it is captured and retained within groove 15.** Thus, since as aforesaid, the maximum diameter of pilot flange 14 is only slightly less than the minimum diameter of the workpiece bore in which it is inserted, and a fortiori, the root and crest diameter of forming threads 12 are equal to, or slightly less, than the crest and root diameters, respectively, of the threads formed in the workpiece bore, **the workpiece material or debris must of necessity be directed to and entrapped in groove 15 thereby prohibiting passage of the aforesaid loosened material or debris either forward of pilot means 14, or rearward of the point where forming threads 12 commence to uniformly reduce in diameter.**"

Rosan, Col. 2 lines 45-62 (emphasis added). Consequently, one of ordinary skill in the art would not be motivated to modify the device of *Rosan* to include a thread spanning from the first end to the second end of the device because doing so would eliminate annular groove 15, rendering the device inoperable for its intended purpose of capturing debris within annular groove 15 during the tapping operation.

Since *Rosan* fails to disclose "at least one continuous and uninterrupted thread . . . helically traversing a length of an exterior surface of the body, the length spanning from the first end to the second end," and since one of ordinary skill in the art would not have been motivated to modify the device of *Rosan* to include a thread spanning from the first end to the

second end of the device, Appellants respectfully contend that Claim 40 and its dependent claims (e.g., Claims 41-43, 46-54, and 72) are allowable over *Rosan*. For analogous reasons, independent Claims 55, and 70 and each of their respective dependent claims (e.g., Claims 56-57, 62-63, and 65-66 and Claim 71) are allowable over *Rosan*.

IV. Claims 40-44, 47, 50, 52-57, 62-63, 66, 70, and 72 are patentable under 35 U.S.C. § 102(b) over *Visotsky*.

a. *Visotsky*, fails to disclose a “continuous and uninterrupted thread . . . helically traversing a length of an exterior surface of the body, the length spanning from the first end to the second end” as recited in Claims 40, 44, 55, and 70.

Claim 40 recites “at least one continuous and uninterrupted thread . . . helically traversing a length of an exterior surface of the body, the length spanning from the first end to the second end.” In the *Office Action*, The Examiner also relies on Figure 1 of *Visotsky* to reject the above-quoted limitations of Claim 40, arguing “(plurality of individual threads 41, each one being uninterrupted seen in fig. 1).” See *Office Action*, page 5, lines 7-9. However, Figure 1 of *Visotsky* shows that its alleged thread is interrupted by a slot 50. See e.g., Fig. 1, Slot 50. As explained by *Visotsky*:

Slot 50 of implant 10 is formed transversely through the implant.

Slot 50 can be filled with autogenous bone, allogenic bone, xenograft bone, demineralized bone, bone paste, cellular material, growth factors, and the like to stimulate healing and remodeling of the implant within the fracture site.

Visotsky, paragraph [0027] (emphasis added). That is, *Visotsky* explicitly discloses that its alleged thread is interrupted by slot 50. Moreover, one of ordinary skill in the art would not be motivated to remove slot 50 from the device of *Visotsky* because doing so would eliminate that device’s ability to be packed with biologic materials, rendering it inoperable for its intended purpose of stimulating healing and remodeling of the implant within the fracture site.

While the Examiner also seems to contend that the above-quoted limitations of Claim 40 are disclosed by a “plurality of threads,” “each one being uninterrupted,” see e.g., *Advisory Action*, page 2, Appellants respectfully point out that none of those alleged threads spans “from the first end to the second end” as recited by Claim 40. Consequently, the “plurality of threads” cited by the Examiner in *Visotsky* fails to disclose “at least one

continuous and uninterrupted thread . . . helically traversing a length of an exterior surface of the body, the length spanning from the first end to the second end.”

Since *Visotsky* fails to disclose “at least one continuous and uninterrupted thread . . . helically traversing a length of an exterior surface of the body, the length spanning from the first end to the second end,” and since one of ordinary skill in the art would not have been motivated to remove slot 50 from the device of *Visotsky*, Appellants respectfully contend that Claim 40 and its dependent claims (e.g., Claims 41-43, 46-54, and 72) are allowable over *Visotsky*. For analogous reasons, independent Claims 44, 55, and 70 and each of their respective dependent claims (e.g., Claims 56-57, 62-63, and 65-66 and Claim 71) are allowable over *Visotsky*.

V. Claim 72 is patentable under 35 U.S.C. § 102(b) over *Simon*.

a. *Simon* fails to disclose “the direction of incline of the leading flank is equal and opposite to the direction of incline of the trailing flank” as recited in Claim 72.

Claim 72 is directed to “[t]he medical implant of Claim 41, wherein the direction of incline of the leading flank is equal and opposite to the direction of incline of the trailing flank.” To reject these limitations, the Examiner relies on surface 17 and buttress 18 illustrated in Figure 5 of *Simon*. See *Office Action*, page 4 lines 4-5. However, *Simon* is completely devoid of any teaching that the direction of incline of surface 17 is equal and opposite to the direction of incline of buttress 18. Rather, *Simon* discloses that “the axial facing surface of the buttress 18 is concavely radiused as at 19.” Moreover, one of ordinary skill in the art would not be motivated to modify the direction of incline of buttress 18 to be equal and opposite to the direction of incline of surface 17 because doing so would reduce or eliminate the threads’ ability buttress the device against a bone. As explained by *Simon*:

[T]he screw thread includes a buttress construction on only one side of the screw thread capable of reinforcing the screw thread so that **forces applied to a graft bone block engaged with the screw thread will be buttressed by the aforesaid buttress construction** forming a part of the screw thread construction.”

Simon, Col. 2 lines 1-8 (emphasis added).

The screw thread includes buttress means on only one side of said screw thread so that **forces applied to the screw thread from a side remote from said buttress means will be buttressed by said buttress means.**

Simon Col. 2 lines 34-37 (emphasis added).

Since *Simon* fails to disclose “the direction of incline of the leading flank is equal and opposite to the direction of incline of the trailing flank,” and since one of ordinary skill in the art would not have been motivated to the modify direction of incline of buttress 18 to be equal and opposite to the direction of incline of surface 17 in the device of *Simon*, Appellants respectfully contend that Claim 72 is allowable over *Simon*.

VI. Claim 43 is patentable under 35 U.S.C. § 102(b) over *Visotsky*.

a. *Visotsky* fails to disclose a “taper angle between 15 degrees and 20 degrees” as recited in Claim 43.

Claim 43 is directed to “[t]he medical implant of Claim 41, wherein the taper angle measures between 15 degrees and 20 degrees.” To reject those limitations, the Examiner relies on *Visotsky*. However, *Visotsky* does not disclose either expressly or inherently a taper angle measuring between 15 degrees and 20 degrees. For at least those reasons, Appellants respectfully contend that Claim 43 is in condition for allowance.

Section 103 Rejections

The Examiner, under 35 U.S.C. § 103(a), rejects Claims 67-69 as allegedly being unpatentable over *Visotsky* in view of the knowledge of one of ordinary skill in the art. See *Office Action*, pages 5-6.

I. Claim 67 and its respective dependent Claims are patentable under 35 U.S.C. § 103 over *Visotsky*.

a. *Visotsky*, fails to disclose a “continuous and uninterrupted thread . . . helically traversing a length of an exterior surface of the body, the length spanning from the first end to the second end” as recited in Claim 67.

As explained above with respect to the § 102(b) rejection of Claim 40 over *Visotsky*, *Visotsky* fails to disclose, “at least one continuous and uninterrupted thread . . . helically traversing a length of an exterior surface of the body, the length spanning from the first end to the second end,” and one of ordinary skill in the art would not have been motivated to modify

the device of *Visotsky* to overcome this deficiency. For at least those reasons, Appellants respectfully contend that Claim 67 and its dependent claims (e.g., Claims 68-69) are in condition for allowance.

II. Claim 69 is patentable under 35 U.S.C. § 103 over *Visotsky*.

a. *Visotsky* does not disclose, teach, or suggest that “the entirety of the medical device is inserted into the sinus tarsi” as recited in Claim 69.

Claim 69 is directed to “[t]he method of Claim 67, wherein the entirety of the medical device is inserted into the sinus tarsi.” To reject those limitations, the Examiner relies on *Visotsky*. See *Office Action*, page 5. However, *Visotsky* does not disclose that the entirety of the medical device is inserted into the sinus tarsi. Rather, *Visotsky* explains that its medical device is only partially inserted partially into a fracture and the remainder of the device is cut away. As explained in *Visotsky*, “[t]he remaining end of the implant, **which is not inserted into the site**, is then cut off by the surgeon using a sagittal saw or similar device.” See *Visotsky* paragraph [0026] (emphasis added). That is, *Visotsky* is devoid of any teaching that the entirety of its medical device is inserted into the sinus tarsi, and further, explicitly teaches away from doing so. For at least those reasons, Appellants respectfully contend that Claim 69 is in condition for allowance.

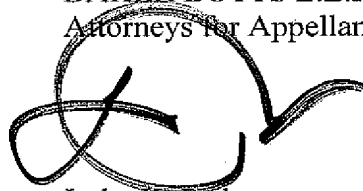
Conclusion

Appellants have demonstrated that the present invention, as claimed, is clearly distinguishable over the prior art cited by the Examiner. Therefore, Appellants respectfully request the Board of Patent Appeals and Interferences to reverse the Examiner's final rejection of the pending claims and instruct the Examiner to issue a notice of allowance of all pending claims.

The Commissioner is hereby authorized to charge the large entity fee of **\$540.00** under 37 C.F.R. § 41.20(b)(2), and to the extent necessary, charge any additional required fees or credit any overpayments to **Deposit Account No. 02-0384 of BAKER BOTTS L.L.P.**

Respectfully submitted,

BAKER BOTTS L.L.P.
Attorneys for Appellants

A handwritten signature in black ink, appearing to be 'L. Pedersen', written over the printed name.

Luke K. Pedersen
Reg. No. 45,003

Dated: 5-26-10

CORRESPONDENCE ADDRESS:

2001 Ross Avenue, Suite 600
Dallas, TX 75201-2980
(214) 953-6655
Customer No. 05073

APPENDIX A: CLAIMS ON APPEAL

Claims 1-39 (Canceled)

40. **(Previously Presented)** A medical implant, comprising:
a headless body configured to fit snugly into a sinus tarsi of a subtalar joint in a human foot, the body comprising:
a first end having a first diameter;
a second end having a second diameter;
at least one continuous and uninterrupted thread including a crest with a substantially flat surface and having a substantially constant thread height and helically traversing a length of an exterior surface of the body, the length spanning from the first end to the second end;
a recessed engagement in the first end; and wherein:
a circumference of the exterior surface tapers from the first diameter to the second diameter along the length of the body; and
the thread includes a leading flank spanning from the crest to a thread root and a trailing flank spanning from the crest to the thread root, the leading flank separated from the trailing flank by a narrowing clearance therebetween.

41. **(Previously Presented)** The medical implant of Claim 40, wherein:
the circumference of the exterior surface tapers uniformly from the first end to the second end according to a predetermined taper angle;
the leading flank and the trailing flank define a constant thread angle therebetween;
and
the direction of incline of the leading flank is opposite the direction of incline of the trailing flank.

42. **(Previously Presented)** The medical implant of Claim 41, wherein the recessed engagement comprises:

- a hexagonal portion;
- a cylindrical portion; and
- a countersink portion.

43. **(Previously Presented)** The medical implant of Claim 41, wherein the taper angle measures between 15 degrees and 20 degrees.

44. **(Previously Presented)** A medical implant, comprising:
- a body adapted for implantation into a sinus tarsi of a subtalar joint in a human foot, the body comprising:
 - a first end having a first diameter;
 - a second end having a second diameter;
 - at least one continuous and uninterrupted thread including a crest with a substantially flat surface and having a substantially constant thread height and helically traversing a length of an exterior surface of the body, the length spanning from the first end to the second end; and
 - a recessed engagement in the first end, the recessed engagement comprising:
 - a hexagonal portion;
 - a cylindrical portion;
 - a countersink portion; and wherein:
 - a circumference of the exterior surface tapers from the first diameter to the second diameter along the length of the body;
 - the taper angle is configured to minimize pressure points between the body and a talus bone and the body and a calcaneus bone when the body is implanted into the sinus tarsi; and
 - the thread includes a leading flank spanning from the crest to a thread root and a trailing flank spanning from the crest to the thread root, the leading flank separated from the trailing flank by a narrowing clearance therebetween.

45. **(Canceled)**

46. **(Previously Presented)** The medical implant of Claim 41, wherein:
the at least one thread has a substantially constant pitch;
the at least one thread further includes a crest width;
the ratio of the crest width to the thread height is at least 0.3;
the thread angle measures approximately 60 degrees; and further comprising:
a thread root width measuring between 0.020 inches and 0.040 inches.

47. **(Previously Presented)** The medical implant of Claim 41, wherein:
the first end comprises a first flat face encircling the recessed engagement; and
the second end comprises a second flat face encircling a bore.

48. **(Previously Presented)** The medical implant of Claim 41, wherein the at least one thread further includes a crest width and a substantially constant pitch, wherein the ratio of the crest width to the pitch is between 0.25 and 0.4.

49. **(Previously Presented)** The medical implant of Claim 41, wherein the at least one thread further includes a thread root width measuring between 0.020 inches and 0.040 inches.

50. **(Previously Presented)** The medical implant of Claim 41, wherein:
the body is generally conical; and
the circumference of the exterior surface comprises the crest of the thread.

51. **(Previously Presented)** The medical implant of Claim 41, wherein:
the taper angle measures approximately 18 degrees;
the thread height is approximately 0.032 inches;
a root width of the thread is approximately 0.030 inches; and
a pitch of the thread is approximately 0.090 inches.

52. **(Previously Presented)** The medical implant of Claim 41, wherein:
the thread is configured to secure the body into the sinus tarsi, and to limit pain caused to a patient by the thread once the medical implant is inserted into the sinus tarsi;
the body is configured to:
reduce calcaneal eversion;
at least partially prevent displacement of a talus without penetrating bone; and
limit pain caused by localized pressure points between the body and one or more surrounding bones once the medical implant is inserted into the sinus tarsi.

53. **(Previously Presented)** The medical implant of Claim 41, wherein:
the entirety of the medical device is adapted for insertion into the sinus tarsi and, once inserted is operable to minimize pressure points between the body and a talus bone and the body and a calcaneus bone when the medical device is implanted into the sinus tarsi.

54. **(Previously Presented)** The medical implant of Claim 41, further comprising a bore coaxial with the recessed engagement and extending from the recessed engagement to the second end.

55. **(Previously Presented)** A method of forming a medical implant, comprising:
configuring a headless body to fit snugly into a sinus tarsi of a subtalar joint in a human foot, the body comprising:

- a first end having a first diameter;
- a second end having a second diameter;

forming at least one continuous and uninterrupted thread including a crest with a substantially flat surface and having a substantially constant thread height and helically traversing a length of an exterior surface of the body, the length spanning from the first end to the second end;

forming a recessed engagement in the first end; and wherein:

a circumference of the exterior surface tapers from the first diameter to the second diameter along the length of the body; and

the thread includes a leading flank spanning from the crest to a thread root and a trailing flank spanning from the crest to the thread root, the leading flank separated from the trailing flank by a narrowing clearance therebetween.

56. **(Previously Presented)** The method of Claim 55, wherein:

the circumference of the exterior surface tapers uniformly from the first end to the second end according to a predetermined taper angle;

the leading flank and the trailing flank define a constant thread angle therebetween;
and

the direction of incline of the leading flank is opposite the direction of incline of the trailing flank.

57. **(Previously Presented)** The method of Claim 56, wherein the recessed engagement comprises:

- a hexagonal portion;
- a cylindrical portion; and
- a countersink portion.

Claims 58 - 61 **(Canceled)**

62. **(Previously Presented)** The method of Claim 56, wherein:
the first end comprises:
a first flat face; and
the second end comprises a second flat face.

63. **(Previously Presented)** The method of Claim 56, further comprising forming
a bore coaxial with the recessed engagement and extending from the recessed engagement to
the second end.

64. **(Canceled)**

65. **(Previously Presented)** The method of Claim 56, wherein the at least one
thread further includes:
the thread angle measuring approximately 60 degrees;
a crest width, wherein the ratio of the crest width to the thread height is at least 0.3;
and
a thread root width measuring between 0.020 inches and 0.040 inches.

66. **(Previously Presented)** The method of Claim 56, wherein:
the body is generally conical; and
the circumference of the exterior surface comprises the crest of the thread.

67. **(Previously Presented)** A method, comprising:
inserting into the sinus tarsi:
a body configured to fit snugly into a sinus tarsi of a subtalar joint in a human foot,
the body comprising:
a first end having a first diameter;
a second end having a second diameter;
a recessed engagement in the first end;
a bore coaxial with the recessed engagement and extending from the recessed
engagement to the second end;
at least one continuous and uninterrupted thread including:
a crest with a substantially flat surface and having a substantially constant thread
height and helically traversing a length of an exterior surface of the body, the length spanning
from the first end to the second end; and
a leading flank inclined away from the second end and spanning from the crest to a
thread root and a trailing flank inclined away from the first end and spanning from the crest
to the thread root, the leading flank and the trailing flank defining a thread angle; and wherein
a circumference of the exterior surface tapers from the first diameter to the second
diameter along the length of the body; and
the thread is configured to secure the body into the sinus tarsi, and to limit pain
caused to a patient by the thread once the body is inserted into the sinus tarsi.

68. **(Previously Presented)** The method of Claim 67, wherein:
the circumference of the exterior surface tapers uniformly from the first end to the
second end according to a first taper angle; the first taper angle defined by a second taper
angle of the sinus tarsi of the second human foot.

69. **(Previously Presented)** The method of Claim 67, wherein the entirety of the
medical device is inserted into the sinus tarsi.

70. **(Previously Presented)** A medical implant, comprising:
a body configured to fit snugly into a sinus tarsi of a subtalar joint in a human foot,
the body comprising:
a first end having a first diameter;
a second end having a second diameter;
a recessed engagement in the first end;
a bore coaxial with the recessed engagement and extending from the recessed engagement to the second end;
at least one continuous and uninterrupted thread including:
a crest with a substantially flat surface and having a substantially constant thread height and helically traversing a length of an exterior surface of the body, the length spanning from the first end to the second end; and
a leading flank spanning from the crest to a thread root and a trailing flank spanning from the crest to the thread root, the leading flank separated from the trailing flank by a narrowing clearance therebetween, the leading flank and the trailing flank defining a thread angle; and wherein
a circumference of the exterior surface tapers from the first diameter to the second diameter along the length of the body; and
the thread is configured to secure the body into the sinus tarsi, and to minimize pain caused to a patient by the thread once the body is inserted into the sinus tarsi.

71. **(Previously Presented)** The medical implant of Claim 70, wherein the body is unperforated along its length.

72 **(Previously Presented)** The medical implant of Claim 41, wherein the direction of incline of the leading flank is equal and opposite to the direction of incline of the trailing flank.

APPENDIX B: EVIDENCE

(NONE)

APPENDIX C: RELATED PROCEEDINGS

The Appellants, the Attorney for Appellants, and the Assignee know of no applications on appeal that may directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.